Management Discussion & Analysis for the Second Quarter of FY 2022-23

Glenmark operates its businesses through three separate entities

Glenmark Pharmaceuticals Ltd. (GPL)

Glenmark Life Sciences (GLS)
(82.84% API subsidiary)

Ichnos Sciences
(100% US based innovation subsidiary)

Each of these three entities operate independently with separate Management Teams and Board of Directors.

Revenue Figures for Glenmark Pharmaceuticals Ltd. (Consolidated)

(Rs. In Millions)

	For the second quarter ended September 30			For the six months ended September 30		
	FY 2022-23	FY 2021-22	Growth (%)	FY 2022-23	FY 2021-22	Growth (%)
India	10,916	9,689	12.7%	21,268	21,940	-3.1%
North America	7,533	7,543	-0.1%	14,161	15,420	-8.2%
Europe	3,785	3,383	11.9%	7,085	6,442	10.0%
Rest of the World1	6,154	7,486	-17.8%	10,380	10,846	-4.3%
API	3,744	3,354	11.6%	6,994	6,394	9.4%
Total	**32,132**	**31,455**	**2.2%**	**59,889**	**61,042**	**-1.9%**
Other Revenue	1,620	20	8153%	1,636	81	1915%
Consolidated Revenue	**33,752**	**31,474**	**7.2%**	**61,525**	**61,123**	**0.7%**

1. Asia, Middle East and Africa, Russia + CIS, and Latin America
2. Average conversion rate in 6M FY 2022-23 considered as INR 78.30 / USD 1.00
   Average conversion rate in 6M FY 2021-22 considered as INR 73.81 / USD 1.00
   USD figures are only indicative

Review of operations for the quarter ended September 30, 2022

For the second quarter of FY23, Glenmark's consolidated revenues from operations was at Rs. 33,752 Mn (USD 425.0 Mn) as against Rs. 31,474 Mn (USD 425.7 Mn) in the corresponding quarter last year, recording growth of 7.2%.

For the six months ended September 30, 2022, Glenmark's consolidated revenue was at Rs. 61,525 Mn (USD 785.8 Mn) as against Rs. 61,123 Mn (USD 828.1 Mn), recording an increase of 0.7%.

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global business with Branded, Generics, and OTC segments in the therapy areas of Dermatology, Respiratory and Oncology. It also has strong regional/country-specific presence in other therapeutic areas like diabetes, cardiovascular and oral contraceptives.

India

Sales from the formulation business in India for the second quarter of FY23 was at Rs. 10,916 Mn (USD 137.2) as against Rs. 9,689 Mn (USD 131 Mn) in the previous corresponding quarter, recording growth of 12.7%. The India business contribution was at 32.3% of the total revenues in Q2 FY23 compared to 30.8% in Q2 FY22.

As per IQVIA MAT September 2022, Glenmark's India formulation business is ranked 14th with a market share of 2.19%. During the quarter, Glenmark's India business continued to strengthen its position in its core therapy areas such as Cardiac and Anti-diabetic in terms of market share. As per IQVIA MAT September 2022, the Cardiac segment market share increased to 5.30% compared to 4.73% last year while the Anti-diabetic segment market share increased to 1.82% compared to 1.79% last year. The dermatology segment market share also increased from 8.12% to 8.16% and the respiratory segment market share changed from 5.30% to 5.27% as per IQVIA MAT September 2022.

As per IQVIA MAT September 2022, the company was ranked 2nd in Dermatology segment, 4th in respiratory segment and increased its ranking to 5th from 6th in cardiac segment. The company has nine brands in the IPM Top 300 brands in the country on the basis of IQVIA MAT September 2022.

The company launched nine new products during the quarter and continued to gain market share in some of the key launches in the cardiac and anti-diabetic segment. The key new launches which are driving growth in the anti-diabetic segment include sitagliptin and its fixed dose combinations with metformin and

dapagliflozin respectively, all of which were launched at the start of the second quarter of FY23. The company has introduced 8 different combinations of sitagliptin based drugs under the brand name SITAZIT® and its variants to increase accessibility to affordable and quality treatment options for patients with uncontrolled type-2 diabetes. In Q1 FY23, Glenmark had also become the first company in India to launch teneligliptin + pioglitazone Fixed-Dose Combination drug for Type 2 Diabetes under the brand name Zita Plus Pio. At the time of launch, it was the only available DPP4 and glitazone combination brand in India. Glenmark has also recently launched a combination of teneligliptin with dapagliflozin.

Recently, Glenmark became the first company in India to launch lobeglitazone 0.5mg, under the brand name LOBG™, for the treatment of uncontrolled type-2 diabetes. With this launch, the company aims to improve glycemic levels in uncontrolled diabetics and create a new pathway to treat insulin resistance in India. Glenmark now has a strong portfolio of products across various levels of interventions for the treatment of Type 2 Diabetes in India.

The company has a healthy pipeline of differentiated products which it plans to launch in the market going forward.

India – Glenmark Consumer Care (GCC) Business

Primary sales for GCC in Q2 FY23 was Rs. 555.7 Mn with growth of 8% mirrored by strong double digit secondary growth of 11%. At YTD September, GCC revenue stands at Rs. 1,203 Mn with YTD September growth of 42%. Our flagship brand Candid Powder™ delivered strong revenue growth of 11% for Q2 FY23 and 44% for H1 FY23. La Shield™ portfolio delivered 31% growth in Q2 FY23 and 113% growth in H1 FY23. Finally, Scalpe+™ portfolio recorded 18% growth in Q2 FY23 and 28% growth in H1 FY23.

North America

North America registered revenue from the sale of finished dosage formulations of Rs. 7,533 Mn (USD 94.8 Mn) for the second quarter of FY23 as against revenue of Rs. 7,543 Mn (USD 102 Mn) for the previous corresponding quarter, recording a decline of 0.1%. North America business contributed 22.3% to the consolidated sales in Q2 FY23, compared to 24.0% in Q2 FY22.

In the second quarter of FY23, Glenmark received final approval for Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules, 1 mg/20 mcg [the generic to Taytulla® Capsules]. The Company filed one ANDA in the second quarter, and plans to file 10-12 ANDAs in FY23.

Glenmark's marketing portfolio through September 30, 2022 consists of 176 generic products authorized for distribution in the U.S. market. The Company currently has 47 applications pending in various stages of the approval process with the US FDA, of which 20 are Paragraph IV applications.

Europe

Glenmark Europe operations' revenue for the second quarter of FY23 was at Rs. 3,785 Mn (USD 47.6 Mn) as against Rs. 3,383 Mn (USD 45.8 Mn) recording a growth of 11.9%. Europe business contributed 11.2% to the total revenues in Q2 FY23 compared to 10.7% in Q2 FY22.

The Company continued to achieve a healthy double digit growth across all key countries in Europe in the second quarter of FY23, in spite of macroeconomic challenges. Glenmark's covered market growth continued to remain strong across both Western Europe and Central Eastern Europe. Base business growth remained strong in Western European markets such as the UK and Germany, while CEE markets such as Poland, the Czech Republic and Slovakia benefited from new product launches in the second quarter. Overall, new product launches across the various markets were as follows: 6 in the CEE markets, 3 in the UK, 1 in the Netherlands, 3 in Germany, 1 in Spain and 4 in the Nordics. The respiratory portfolio in Europe also continues to gain market share across both WEU and CEE countries.

ROW Region (Asia, MEA, LATAM and RCIS)

For the second quarter of FY23, revenue from the ROW region was Rs. 6,154 Mn (USD 77.7 Mn) as against Rs. 7,486 Mn (USD 101.3 Mn) for the previous corresponding quarter, recording a decline of 17.8%. The decline is on account of the high base last year due to strong sales of the COVID portfolio in Q2 FY22; adjusted for that, the region recorded 15%+ growth in Q2 FY23. ROW business contributed 18.2% to the total revenues in Q2 FY23 compared to 23.8% in Q2 FY22.

While the overall macroeconomic situation continues to remain challenging, the pharmaceutical market in Russia has been stable and provided opportunities for growth. Overall, Glenmark's Russia business recorded a positive trend in the second quarter. For the month of September 2022, Glenmark outperformed the Retail market by value (+6.5% vs +2.9%). Furthermore, Glenmark gained +2 positions and was ranked 48th on retail market in September 2022, Glenmark also gained +3 positions and was ranked 8th on the Dermatology market, while it continued to be ranked 2nd in the Expectorants market in Russia. Business growth has been aided by strong performance in key products across the Dermatology market, as well as additional promotion on the new indication for Ryaltris.

Asia region recorded subdued growth in the second quarter. While markets such as Malaysia and the Philippines recorded double-digit secondary growth, multiple headwinds in other Asian countries led to

lower growth across Myanmar, Vietnam and Sri Lanka. As per IQVIA MAT June 2022 data for the Philippines, Malaysia and Sri Lanka markets in Asia, Glenmark is ranked 6th in the overall covered market, and is ranked 1st in the Dermatology segment. Our partner Yuhan Corporation received approval for Ryaltris in South Korea towards the end of the second quarter. Also, Ryaltris continues to do well in Australia and the Philippines.

The Middle East and Africa region recorded 21% growth in secondary sales during the second quarter of FY23. While growth in Kenya was marginally impacted by macro-economic factors, Glenmark continued to achieve strong secondary sales growth of 30%+ in South Africa and Saudi Arabia. As per IMS MAT September 2022 data, Glenmark is ranked 3rd amongst all generic pharmaceutical companies in Kenya.

LATAM witnessed growth of 22% at the regional level with most of the markets recording good growth during the second quarter. The respiratory portfolio in the LATAM market continued to gain significant scale, particularly in Brazil and Mexico. The Company is planning to launch additional products in the region to further augment the overall portfolio.

Respiratory – Creating Global Scale

Following are the key business updates for Glenmark's global respiratory business in Q2 FY23:

Ryaltris™

- In FY23, Ryaltris is targeted to be approved / launched in 34 markets globally. As of September 30, 2022, Ryaltris has received approval / been launched in 16 markets, and is awaiting approval in 18 markets which are expected to be received in H2 FY23
- Glenmark's partner, Hikma, commercially launched Ryaltris in the US in August 2022
- In Q2 FY23, Glenmark supplied product to its partner in South Korea, Yuhan Corporation, to enable commercial launch of Ryaltris in October 2022
- Following approval in Canada, Glenmark's partner, Bausch intends to launch the product in Q4 FY23
- Additionally, during the second quarter, Glenmark received MA grants for Ryaltris in Malaysia, Kazakhstan, Moldova and Dominican Republic; and also submitted the MA application in Vietnam and Zimbabwe. The company is awaiting regulatory approvals for its filings in Brazil, Mexico, Vietnam and several other emerging markets.
- Ryaltris sales continue to grow in Australia, United Kingdom, Czech Republic, Poland, Italy, Ireland, Russia, Ukraine, Uzbekistan, South Africa, Philippines, Peru and Ecuador
- Glenmark's partner in EU, Menarini, intends to launch the product in H2 of FY23 in additional key European markets
- Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., made significant

progress on the enrollment in the Phase 3 study in China, with approximately 70% of the recruitment being completed by end of Q2. Grand Pharma aims to complete the study by mid-2023 and submit the NDA application by end of 2023

Other key products

- Clinical trial ongoing for generic Flovent pMDI; Expect to file in CY23
- Plan to file at least one more generic respiratory pMDI in the US in CY23 and continue filing momentum beyond FY24

Innovative R&D Pipeline

GRC 54276

GRC 54276 (HPK1 Inhibitor) is the company's oncology pipeline asset being developed as an orally administered IO-adjuvant treatment for patients with solid tumors in oncology. A Phase 1 dose escalation study is ongoing in India as per plan. Successfully recruitment of patients in Cohort 1 was completed in Q2 FY23. No dose limiting toxicities were observed in the first cohort; subsequently Cohort 2 has been initiated, and in total, 10 patients have been dosed with the drug.

GRC 39815

GRC 39815 (RORγt inhibitor) is the company's respiratory pipeline asset being developed as an inhaled therapy for treatment of mild to moderate Chronic Obstructive Pulmonary Disorder (COPD), currently under Phase 1 clinical development in the US.

GLENMARK LIFE SCIENCES LTD. (GLS)

Glenmark Life Sciences is focused on manufacturing and marketing of Active Pharmaceutical Ingredient (API) products across all major markets globally. It also includes captive sales (i.e. use of API by GPL for its own formulations).

Revenues from operations including captive sales were Rs. 5,093 Mn as against Rs. 5,618 Mn, recording a YoY decline of 9.3% due to high base last year. During Q2 FY23, regulated markets contribution increased to 73.6% with growth of 7.1% QoQ. Emerging markets remained stable YoY (ex-COVID). CDMO business recorded strong growth of 27.2% QoQ. GLS filed 4 DMFs / CEPs during the second quarter. GLS also made progress in the ongoing capacity expansion initiatives across Ankleshwar and Dahej.

External sales for Glenmark Life Sciences in Q2 FY23 were at Rs. 3,744 Mn (USD 47.1 Mn) as against Rs. 3,354 Mn (USD 45.4 Mn) in Q2 FY22, recording a growth of 11.6% YoY.

For further updates on the organization, please log on to www.glenmarklifesciences.com.

ICHNOS SCIENCES Inc.

Glenmark has invested Rs. 1,727 Mn (USD 22 Mn) in the second quarter of FY23 compared to Rs 1,850 Mn (USD 25 Mn) in the corresponding quarter last year. For the first six months of FY23, Glenmark has invested Rs. 3,363 Mn (USD 43 Mn) compared to Rs. 3,467 Mn (USD 47 Mn) invested in the corresponding period of the previous financial year.

For further updates on the pipeline and the organization, please log on to www.ichnossciences.com. The pipeline update for the second quarter of FY23 is published on this website.

KEY OBJECTIVES FOR FY23

- Revenue growth of 6-8% during the year
- Sustain EBITDA margin performance at similar levels of FY22
- Capex of Rs. 7-8 Bn
- Strategic priority to enhance free cash generation for further debt reduction
- Close 1-2 out-licensing agreements in innovation pipeline

Disclaimer

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ICHNOS SCIENCES INC.

NOVEMBER 2022 UPDATE

ABOUT ICHNOS

Ichnos Sciences aims to shift the way the world thinks about innovation in medicine by developing potentially transformative biologic treatments in immuno-oncology. The company, currently a subsidiary of Glenmark Holding, SA, plans to pursue external financing following achievement of clinical proof of concept for its lead assets.

Headquartered in New York City, Ichnos has discovery and manufacturing operations at two sites in Switzerland. As a fully integrated biotechnology company with approximately 225 employees, Ichnos has strong capabilities in research, antibody engineering, CMC, and clinical development of biotechnologies.

Ichnos is guided by an accomplished management team with experience developing immune cell engagers within the biopharmaceuticals industry, and is led by Cyril Konto, M.D., President and Chief Executive Officer.

CYRIL KONTO, M.D. President and Chief Executive Officer Allogene, Pfizer, Bristol Myers Squibb	**ERIC J. FELDMAN, M.D.** Chief Medical Officer GlycoMimetics, Inc., Amphivena	**ROBERTO GIOVANNINI, Ph.D.** Chief Process and Manufacturing Officer Boehringer Ingelheim, Glenmark
PATRICIA JAQUET Global Head of Human Resources COVANCE	**GRACE MAGUIRE** Head of Communications and Corporate Affairs Forest Laboratories, Inc., Wyeth	**ASHOK MARÍN** General Counsel sanofi, GILEAD
MICHAEL D. PRICE Chief Financial Officer AKCEA, novelion	**EUGENE ZHUKOVSKY, Ph.D.** Chief Scientific Officer AFFIMED, BIOMUNEX, xencor, Boehringer Ingelheim	

The proprietary BEAT® technology platform[1] is the basis for Ichnos' clinical-stage oncology pipeline. Using this technology, coupled with the proprietary common light chain library, the company is developing novel multispecific immune cell engagers and modulators, with the goal of realizing its mission to provide breakthrough, potentially curative therapies that may extend and improve lives, writing a new chapter in healthcare.

ONCOLOGY PIPELINE

The first wave of Ichnos' multispecific antibody pipeline consists of five programs targeting a range of hematologic malignancies and solid tumor indications through engagement of a broad spectrum of immune cells. The most advanced programs are ISB 1342, a clinical-stage, potentially first-in-class bispecific antibody targeting CD38 and CD3, which is in Phase 1 for the treatment of relapsed/refractory multiple myeloma, and ISB 1442, a biparatopic bispecific antibody targeting CD38 and CD47, currently in a Phase 1/2 dose escalation/expansion study for the same indication. The first patient in the study for ISB 1442 was dosed this past quarter, in September 2022.

Ichnos is looking for asset-level and platform-level collaboration partners in development and research. For more information, email us at Partnership@IchnosSciences.com.

MOLECULE MECHANISM/CLASS	PHASE/STATUS	LEAD INDICATION
ISB 1342 CD38 x CD3 BEAT® 1.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma; T-ALL is also under consideration
ISB 1442 CD38 x CD47 BEAT® 2.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma; AML is also under consideration
ISB 2001 BCMA x CD38 x CD3 TREAT™ trispecific antibody[2]	IND-Enabling Studies	Relapsed/Refractory Multiple Myeloma
ISB 2004 BEAT® 2.0 bispecific antibody	Discovery	Hematologic Malignancies/ Solid Tumors
NK-cell engaging multispecific platform (formerly ISB 2005)	Discovery	Solid Tumors

[1] Bispecific Engagement by Antibodies based on the TCR
[2] Trispecific Engagement by Antibodies based on the TCR

OVERVIEW OF SELECT ONCOLOGY DRUG PRODUCT CANDIDATES

ISB 1342 (CD38 X CD3 BISPECIFIC ANTIBODY)

- A Phase 1, open-label, dose-escalation, first-in-human study of ISB 1342 in patients with relapsed/refractory multiple myeloma is ongoing.
  - Enrollment of patients receiving a weekly dosing regimen is ongoing.
  - Number of sites participating in the study was expanded at the end of calendar year 2021 to enhance enrollment. New locations in the U.S. were added and 11 sites were opened for enrollment in France and are now recruiting subjects.
  - Clinical proof of concept in the ongoing study is anticipated towards the end of calendar year 2022, or in early 2023.
- The primary objectives of the study are to:
  - Determine maximum tolerated dose and/or recommended Phase 2 dose of ISB 1342 (Part 1 dose escalation).
  - Assess anti-myeloma activity of ISB 1342 according to the International Myeloma Working Group response criteria (Part 2 dose expansion).
- Clinical data on this ongoing Phase 1 study will be presented at the American Society of Hematology (ASH) Annual Meeting in December 2022:
  - Initial Results of Dose Escalation of ISB 1342, a Novel CD3 x CD38 Bispecific Antibody, in Patients with Relapsed / Refractory Multiple Myeloma (RRMM); Poster presentation on Sunday, December 11 from 6:00PM – 8:00PM CST
- ISB 1342 was granted Orphan Drug Designation for multiple myeloma by the FDA.
- The bulk drug substance is manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.

ISB 1442 (CD38 X CD47 BISPECIFIC ANTIBODY)

- This first-in-class biparatopic bispecific antibody targeting CD38 x CD47 was generated using the BEAT® 2.0 technology developed by scientists in Ichnos' laboratories in Lausanne at the Biopole life sciences campus.
- ISB 1442 is designed to kill CD38-expressing tumor cells through inhibition of the CD47-SIRPα axis to increase antibody-dependent cellular phagocytosis (ADCP) and enhance antibody-dependent cellular cytotoxicity (ADCC) as well as complement-dependent cytotoxicity (CDC).
- An IND was filed with the US Food and Drug Administration earlier this calendar year and a Phase 1/2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple

myeloma began dosing patients in September 2022. Ichnos also plans to develop ISB 1442 in other hematologic malignancies such as acute myeloid leukemia (AML).

- The preclinical data package for ISB 1442, which may be viewed at this link, shows:
  - Higher potency in vitro for ISB 1442 relative to daratumumab in CD38 high/low tumor models as measured by a multiple antibody-dependent mechanisms of action killing assay
  - Higher tumor growth inhibition for ISB 1442 than daratumumab in CD38 high preclinical in vivo xenograft models
  - Low on-target off-tumor binding with ISB 1442 compared to anti-CD47 mAb (5F9), is anticipated to result in lower red blood cell depletion in clinic, and potentially a better therapeutic index than anti-CD47 bivalent monoclonal antibodies
- Additional information on the ongoing Phase 1 study and on preclinical models in other hematologic malignancies will be presented at the ASH Annual Meeting in December 2022:
  - A Phase 1/2, First-in-Human, Multicenter, Open-Label, Dose Escalation and Dose-Expansion Study of Single-Agent ISB 1442 in Patients with Relapsed/Refractory Multiple Myeloma; Poster presentation on Monday, December 12 from 6:00PM – 8:00PM CST
  - Preclinical Evaluation of ISB 1442, a First-in-Class CD38 and CD47 Bispecific Antibody Innate Cell Modulator for the Treatment of AML and T-ALL; Poster presentation on Sunday, December 11 from 6:00PM – 8:00PM CST
- The first bulk drug substance batches to support IND filing and the ongoing Phase 1/2 dose escalation and expansion study were manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland in 2021.

ISB 2001 TREAT™ TRISPECIFIC ANTIBODY

- ISB 2001 is the first T cell-engaging antibody that targets BCMA and CD38 on multiple myeloma cells. It is a trispecific antibody based on TREAT™ technology, a proprietary platform allowing maximal flexibility and manufacturability of full-length multispecific antibodies. Additional ISB 2001 details include:
  - ISB 2001 combines three proprietary fragment antigen-binding arms, each targeting a different antigen, with one arm binding to the epsilon chain of CD3 on T cells, and the other two binding BCMA and CD38 on myeloma cells. Its Fc domain was fully silenced to suppress Fc effector functions.
  - In vitro studies showed that ISB 2001 exhibited increased killing potency of tumor

cells compared to all tested antibodies that are either currently approved for the treatment of multiple myeloma or are being tested in ongoing clinical studies. In vivo studies in the multiple myeloma models also demonstrated superior potency of ISB 2001 relative to approved antibody treatments of multiple myeloma.

  - ISB 2001 redirects CD3+ T lymphocytes to kill tumor cells expressing low to high levels of both BCMA and CD38. With two different tumor-associated antigens instead of one, ISB 2001 has increased binding specificity to multiple myeloma cells due to enhanced avidity-based binding and is also expected to be more resistant to antigen escape associated with treatment of multiple myeloma patients.

- The preclinical data package for ISB 2001 was selected for oral presentation at the ASH Annual Meeting on Saturday, December 10 at 5:00PM CST:

  - ISB 2001, a First-in-Class Trispecific BCMA and CD38 T Cell Engager Designed to Overcome Mechanisms of Escape from Treatments for Multiple Myeloma by Targeting Two Antigens

- Currently in IND-enabling studies, Ichnos intends to file an Australian CTN and US IND for ISB 2001 in the first quarter of calendar year 2023 and is considering expansion of clinical studies to additional countries in parallel.

- The first bulk drug substance batches to support IND filing and the Phase 1 dose escalation and expansion study were manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland in 2022.

AUTOIMMUNE DISEASES

Ichnos has two monoclonal antibody drug product candidates addressing autoimmune diseases in the pipeline. In order to enhance the company's focus on oncology, future development of both assets will be overseen by out-licensing partners.

The first asset, ISB 880, an anti-IL-1RAP antagonist, was licensed to Almirall, S.A. in December 2021. Initiation of dosing in a Phase 1 study of ISB 880 was announced by Almirall in September 2022. The second antibody, ISB 830 (telazorlimab), an OX40 antagonist that completed a Phase 2b study in moderate to severe atopic dermatitis in calendar year 2021, is in partnering discussions. Both compounds have potential across a range of autoimmune diseases.

ASSETS IN AUTOIMMUNE DISEASE

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS
ISB 880 (ALM 27134) IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	Phase 1	Licensed to Almirall S.A. in December 2021. Dosing of participants in the Phase 1 study was announced by Almirall in September 2022.
ISB 830 Telazorlimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Successfully completed a Phase 2b study in Atopic Dermatitis. Exploring partnership(s).
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	

ISB 880 (IL-1RAP ANTAGONIST)

- Ichnos entered an exclusive global licensing agreement for ISB 880 in autoimmune diseases with Almirall in December 2021. Within the terms of the agreement, Almirall assumed full cost and responsibility for the global development and commercialization of the compound. Ichnos received an upfront payment of €20.8 million. The deal includes development and commercial milestone payments and tiered royalties based upon future global sales. As part of the agreement, Ichnos is also being paid to manufacture batches of ISB 880 to support early clinical studies to be sponsored by Almirall and realized revenue this year for drug supplies for the ongoing Phase 1 study.

- ISB 880, a fully-human, high-affinity, monoclonal antibody blocking IL-1RAP signaling, has completed IND-enabling studies for patients with autoimmune diseases. The optimal antibody profile, the strong *in vitro* and *in vivo* data package, as well as toxicology, CMC, and clinical pharmacology plans enabled U.S. IND filing by Almirall, and a Phase 1 study is under way.
- Blockade of IL-1RAP simultaneously abrogates multiple disease drivers among the IL-1 family of proinflammatory cytokine receptors, including IL-1R, IL-33R, and IL-36R, differentiating ISB 880 from single cytokine blockade therapies. These cytokines have been implicated in numerous autoimmune conditions, opening opportunities for ISB 880 to be positioned across broad disease indications.
- To date, there is no IL-1RAP antagonist approved or under clinical development for autoimmune disease, positioning ISB 880 as a potential first-in-class therapeutic.
- Ichnos retains rights for antibodies acting on the IL-1RAP pathway for oncology indications.

ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)

- The database for the ISB 830-204 Phase 2b clinical study in atopic dermatitis was locked in October 2021, and the final results were posted on ClinicalTrials.gov. This study, which was conducted in the U.S., Canada, Germany, Czech Republic, and Poland, had a randomized, controlled, multicenter design and assessed three doses and two dosing schedules of telazorlimab versus placebo in adults with moderate-to-severe atopic dermatitis.
- Results from the double-blind portion of the study are summarized below:
    - **Efficacy:** The primary endpoint of the EASI score, % change from baseline to Week 16, was achieved for the two highest doses of telazorlimab tested (300 mg and 600 mg q 2 weeks) versus placebo.
    - **Safety:** Telazorlimab was well tolerated. The most commonly reported adverse events (>5%) were atopic dermatitis, nasopharyngitis, upper respiratory tract infection, and headache. One patient with pre-existing hypertension in the telazorlimab group died due to a presumed cardiovascular event during the treatment period. The investigator considered the death to be unrelated to the study drug.
- Ichnos has clearance from the FDA to study telazorlimab in seropositive autoimmune diseases (Rheumatoid Arthritis, Systemic Lupus Erythematosus, Sjogren's Syndrome, Multiple Sclerosis, Type I Diabetes Mellitus, Myasthenia Gravis), and is actively seeking a partner to further develop the drug in atopic dermatitis and other indications. For more information, email us at Partnership@IchnosSciences.com.